MAY 15 2002

K020771

7. 510(k) SUMMARY

This 510 (k) summary is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

The Assigned 510(k) number is K020771.

Submitter:

ACON Laboratories, Inc.
4108 Sorrento Valley Boulevard
San Diego, California 92121

Tel.: 858-535-2030
Fax: 858-535-2038

Date:

March 4, 2002

Contact Person:

Edward Tung, Ph.D.

Product Names:

ACON® One Step Drug Screen Test Card
ACON® One Step Drug Screen Test Card with Integrated Cup

Common Name:

Immunochromatographic test for the qualitative detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and barbiturate in human urine.

Device Classification:

The ACON One Step Drug Screen Test Card ACON and ACON One Step Drug Screen Test Card with Integrated Cup is similar to other FDA-cleared devices for the qualitative and simultaneous detection of drugs in urine specimens. These drug test devices are used only to provide a preliminary analytical result (21 CFR 862.3650). The test systems have been classified as Class II devices with moderate complexity. Product codes LDJ, DIO, LAF, DKZ, DJG, LCM, JXM, DJR, and DIS have been assigned for the test system.

Classification Name:

Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and barbiturate test systems

Intended Use:

The ACON One Step Drug Screen Test Card and ACON One Step Drug Screen Test Card with Integrated Cup are rapid chromatographic immunoassay devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine. The test is calibrated using analytes with their respective cutoff concentrations listed in the following table.

Test	Calibrator	Cut-off
Amphetamine (AMP)	D-Amphetamine	1,000 ng/mL
Barbiturates (BAR)	Secobarbital	300 ng/mL
Benzodiazepines (BZO)	Oxazepam	300 ng/mL
Cocaine (COC)	Benzoylecgonine	300 ng/mL
Methamphetamine (mAMP)	D-Methamphetamine	1,000 ng/mL
Morphine (MOP 300 or OPI 300)	Morphine	300 ng/mL
Methadone (MTD)	Methadone	300 ng/mL
Opiates (OPI 2000)	Morphine	2,000 ng/mL
Phencyclidine (PCP)	Phencyclidine	25 ng/mL
Marijuana (THC)	11-nor-Δ^9-THC-9 COOH	50 ng/mL

The configurations of the ACON One Step Multi-Drug Screen Test Card and ACON One Step Multi-Drug Screen Test Card with Integrated Cup come with any combination of the above listed drug analytes. They are intended for the healthcare professionals including professionals at point-of-care sites.

Description:

The ACON One Step Drug Screen Test card are competitive binding, lateral flow immunochromatographic assays for the qualitative and simultaneous screening of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine.

The test is based on the principle of antigen-antibody immunochemistry. It utilizes mouse monoclonal antibody to selectively detect elevated levels of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in urine. These tests can be performed without the use of an instrument.

A drug-positive urine specimen will not generate a colored-line in the designated test region, while a negative urine specimen or a urine specimen containing the drug concentration below the cut-off level will generate a colored-line in the test region. To serve as a procedural control, a colored-line will always appear at the control region, indicating that proper volume of specimen has been applied and membrane wicking has occurred.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

Edward Tung, Ph.D.
Director of Regulatory Affairs
ACON Laboratories, Inc.
4108 Sorrento Valley Blvd.
San Diego, CA 92121

MAY 15 2002

Re: k020771
Trade/Device Names: ACON® One Step Drug Screen Test Card
ACON® One Step Drug Screen Test Card with Integrated Cup
Regulation Numbers: 21 CFR 862.3610; 21 CFR 862.3650; 21 CFR 862.3100; 21 CFR 862.3150; 21 CFR 862.3170; 21 CFR 862.3870; 21 CFR 862.3250; 21 CFR 862.3640; 21 CFR 862.3620
Regulation Names: Methamphetamine test system; Opiate test system; Amphetamine test system; Barbiturate test system; Benzodiazephine test system; Cannabinoid test system; Cocaine and cocaine metabolite test system; Morphine test system; Methadone test system
Regulatory Class: Class II
Product Codes: DJG; LCM; DKZ; DIS; JXM; LDJ; DIO; DPK; DJR
Dated: March 6, 2002
Received: March 8, 2002

Dear Dr. Tung:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4639. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

10. INDICATIONS FOR USE

510(k) Number: K020771

Device Name: ACON One Step Drug Screen Test Card
ACON One Step Drug Screen Test Card with Integrated Cup

Indications for Use:

The ACON One Step Drug Screen Test Card and ACON One Step Drug Screen Test Card with Integrated Cup are rapid chromatographic immunoassay devices for the qualitative and simultaneous detection of Marijuana, Cocaine, Methamphetamine, Amphetamine, Opiates, Phencyclidine, Benzodiazepine, Methadone, and/or barbiturate in human urine. The test is calibrated against analytes with their respective cutoff concentrations listed in the following table.

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(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K020771

(Please do not write below this point)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ Or over-the-counter Use _____

(Per 21 CFR 801.109)